

## **DETAILED ACTION**

### ***Species Election Requirement***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicant is required to elect a single disease to be treated in order to assist in beginning examination.

The species of disease to be treated are as follows, disclosed in claims 26, 28, 29, 32, 34, 35, 36, 37 and 38:

ankylosing spondylitis,  
Reiter's syndrome,  
psoriatic arthritis,  
osteoarthritis or degenerative joint disease,  
rheumatoid arthritis,  
Sjogren's syndrome,  
Behcet's syndrome,  
relapsing polychondritis,  
systemic lupus erythematosus,  
discoid lupus erythematosus,  
systemic sclerosis,  
eosinophilic fasciitis,  
polymyositis and dermatomyositis,

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polymyalgia rheumatica,  
vasculitis,  
temporal arteritis,  
polyarteritis nodosa,  
Wegner's granulomatosis,  
mixed connective tissue disease,  
juvenile rheumatoid arthritis,  
Crohn's disease,  
ulcerative colitis,  
irritable bowel syndrome (spastic colon),  
fibrotic conditions of the liver,  
inflammation of the oral mucosa (stomatitis),  
recurrent aphthous stomatitis,  
multiple sclerosis,  
Alzheimer's disease,  
ischemia-reperfusion injury associated with ischemic stroke,  
asthma,  
chronic obstructive pulmonary disease,  
adult respiratory distress syndrome,  
contact dermatitis,  
atopic dermatitis,  
psoriasis,

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pityriasis rosea,  
lichen planus,  
pityriasis rubra pilaris,  
an inflammatory condition related to tissue trauma,  
an inflammatory condition resulting from organ transplantations or other surgical  
operations,  
diabetes,  
atherosclerosis,  
vascular retinopathies,  
retinopathy,  
nephropathy,  
nephrotic syndrome,  
polyneuropathy,  
mononeuropathies,  
autonomic neuropathy,  
foot ulcers,  
joint problems,  
atherosclerosis,  
obesity,  
atheromatous atherosclerosis,  
nonatheromatous atherosclerosis,  
ischemic heart disease,

peripheral arterial occlusion,  
thromboangiitis obliterans (Buerger's disease), or  
Raynaud's disease.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Applicant is cautioned that elections of a genus, such as "inflammatory disease" or "gastrointestinal inflammatory disease", will be considered non-responsive.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic or sub-generic to the disease to be treated.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The common feature of the inventions is the administration of an aminoglycoside compound of claim 20. However, such the administration of an aminoglycoside is a known product. See Riordan et al. (WIPO Publication WO 03/007938, provided by Applicant in IDS filed 18 May 2006), page 1 lines 6-7 and page 3, lines 13-14 and 16-18. Therefore the special technical feature of each species is the specific disease to be treated.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSL

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